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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/933,709
Filing Date: August 22, 2001
Appellant(s): MORRIS ET AL.

William E. Kuss
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6-20-08 appealing from the Office action mailed 6-21-07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. The amendment after final was not entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct. However, upon consideration, the 112, 2nd paragraph rejection of claims based on the term, 'at least' is withdrawn. Although the 112, 2nd paragraph rejection is made with respect to claim 23 which recites B vitamins along with fat soluble vitamins, the examiner will drop the rejection in view of applicant's willingness to delete these vitamins from claim 23.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,486,435	SCHMIDT	12-1984
4,603,143	SCHMIDT	7-1986
4,719,228	RAWLINS	1-1988
4,010,073	DRAKE	3-1977

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant amends claim 22 to recite 'fat soluble vitamin'; the dependent claim 23 recites B vitamins. These are hydrophilic and not fat soluble vitamins.

2. Claims 18-44 and 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al (4,486,435) in combination with Schmidt (4,603, 143) and Rawlins (4,719,228) or Rawlins in view of Schmidt (4,486,435) or Schmidt (4,719,228) by themselves or in combination.

Schmidt et al. teach a free-flowing, non-agglomerated, non-caking vitamin powder composition comprising about 45 to about 60 percent vitamin, about 2 to about l 8 percent of corn starch, about 0.2 to about 2 percent hydrophobic silica, and other ingredients (col. 8, lines 15-22; col. 5, example 1). Schmidt et al. further teach that the water insoluble carrier can be corn starch (col. 8, line 32). Schmidt et al. also teach that the vitamin can be selected from vitamin H, D, E, K and mixtures thereof as well as

vitamin B1, B6, B2, B12, C and mixtures thereof (col. 2, lines 20-34). Lastly, Schmidt et al. teach that the vitamin composition of their invention is suitable for the preparation of tablets (col. 1, line 49). The reference does not specifically discuss stability. However, it is the position of the examiner that absent evidence to the contrary, the formulation must provide appropriate stability, or it would be useless for its intended purpose. What are lacking in Schmidt are the claimed particle sizes of silica.

As discussed before, Schmidt 143 while disclosing free flowing, high density, fat-soluble vitamin powder preparations teaches the use of silica of bigger particle sizes (100 microns). The vitamins include tocopherols, vitamins A, D and K (abstract, col. 2, line 49 through col. 3, line 26, Table 1, Examples and claims).

Rawlins teaches free flowing powders of pharmaceutical agents. According to Rawlins, the silica particles can have a diameters of at lest 10 microns and preferably between 10 microns to 1 mm (abstract, col. 1,lines 48-50; col. 2, lines 24-32; lines 43-47; Example 2 and claims). Example 2 in particular shows the use of silica of diameter 50 microns (Sipernat 50)

It would have been obvious to use the silica of bigger particle sizes 40-50 microns in the compositions of Schmidt et al 435 or 143 with a reasonable expectation of success, since as evidenced by Rawlins, one can obtain free-flowing powders using silica which has a diameter between 10 microns to 1 millimeter, in particular 50 microns. Although the references are silent with respect to the density and the surface area of the silica particles, since these are commercially available particles and in the absence of showing otherwise and the criticality of these factors, it is the position of the examiner

that Rawlins's silica particles which were obtained commercially possess these properties or manipulatable parameters to obtain the best possible results.

Alternately, the use of vitamins D, E or K as the active agents in the compositions of Rawlins who teaches free flowing powders of active agents with silica particles of 50 microns with the expectation of obtaining similar results since the references of Schmidt (435) and (143) each teach that they are free flowing powders of these vitamins can be prepared using silica particles.

3. Claims 18-44 and 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al (4,486,435) in combination with Schmidt (4,603, 143) and Rawlins (4,719,228) or Rawlins in view of Schmidt (4,486,435) or Schmidt (4,719,228) by themselves or in combination as set forth above, further in view of Drake (4,010,073).

The teachings of Schmidt (435), (143) and Rawlins have been discussed above. What is lacking in these references is the teaching that the starch used is a redried starch.

Drake while disclosing free-flowing powders of an enzyme composition teaches that commercial starch generally contains between 10 to 14 % moisture and the resultant product has poor storage stability. Drake further teaches that redried starch with moisture content of 3 % is commercially available and that it increases the storage stability. The compositions of Drake further include silica (abstract, col. 2, lines 29-51, examples and claims).

The use of redried starch instead of starch in the teachings of Schmidt (435), (143) and Rawlins would have been obvious to one of ordinary skill in the art since Drake teaches high moisture content of regular starch which leads to poor storage stability and hence the use of redried starch.

Applicant's arguments have been fully considered, but are not persuasive. The examiner has already addressed applicant's arugments pertaining to the primary references.

(10) Response to Argument

Rejection 1*:* This rejection will be dropped since applicant expresses the willingness to delete the B vitamins from the claim.

Rejection 2: Applicant's arugments have been fully considered, but are not persuasive. Applicant argues that the office action has noted that the claims are non-obvious where there is a showing of criticality of the range 40-50 microns for silica and/or the additional physical characteristics of the silica sizes shown to be effective and the results in the declaration of Morris shows that only 40-50 micron range resulted in a free-flowing powder. Further according to applicant, the results are entirely unexpected and that claims 22 and 26 have been amended to recite the high fat-soluble vitamin loading density, which is achieved unexpectedly. These arguments are not persuasive. First of all, the examiner points out that results presented are not evaluated using scientific measuring parameters to show that the properties are patentably distinct and unexpected. The results such as good, fair, very good, no and yes are merely observations, which are subjective and not scientific (see Table). The last column in the

Table merely states, 'acceptance fro processing' with results as 'no' and 'yes'. It is unclear was to what it means. Secondly, according to Rawlins who uses the same Sipernat 50 (50 microns), the powders are free flowing. Third, the results also appear to show that the results depend upon which company the silica is obtained from. For example, Aerosil 200, 12 microns is gritty and Aerosil R 972, 16 microns is very gritty. If increase in sizes produces free flowing powders, then one would assume that 16 micron silica to be better than 12 micron particles. Furthermore, if the particle sizes are that critical and if 50 micron silica shows different results from that of 100, one would expect different or same results with 40 micron particles from those obtained from 50 micron particles. No results are presented for 40-micron particles. Finally, col. 3 shows 'oil absorption'. Among the vitamins, B vitamins, vitamin A, beta-carotene are solids and not oils. Applicant has not shown that the silica particles having solids behave the same way as oily vitamins. In response applicant states that "despite the submission of the declaration of Morris, the examiner asserts that the declaration is unscientific. Applicants strongly disagree with the characterization of the data in the declaration of Morris as being "unscientific" and such a characterization of the data is contrary to logic, reason and the text itself. According to applicant Mr. Morris is an expert in his field and the declaration contains scientific data that was collected in the course of the controlled experiment and further, the data is submitted under oath. These arguments are not persuasive since the examiner is not questioning whether Mr. Morris is an expert in the field or not. The examiner is only determining whether the results observed are patentably distinct and whether they are unexpected. It is unclear to the examiner how

one can determine these factors with results expressed in qualitative parameters such as good, fair, very good, no and yes. With regard to applicant's arguments that the record clearly establishes that the declaration of Morris shows that the 40-50 micron range is critical to forming a free-flowing powder, the examiner respectfully points board's attention to Rawlins (4,719,228) which shows that the particles obtained using the ***same Sipernat 50 are freely flowable powders*** (see abstract).

Applicant argues that the examiner states that the 228 patent teaches that Sipernat 50 is free-flowing and this is an incorrect reading of the reference since 228 teaches that silica ranging from 10 micrometers to 1 mm in combination with pharmaceutically active ingredient, but 228 does not teach or suggest combining silica with a fat soluble vitamin. These arguments are not persuasive. Although 228 teaches one could use 10 microns to 1 mm, in all the examples (1-5) it uses only Sipernat 50 and therefore, one could assume that it is the preferred silica and the statements in 228 that the compositions are 'free-flowing' refers to compositions containing this silica. With regard to applicant's arguments that 228 does not teach fat soluble vitamins, the examiner points out that the primary references teach the use of silica for fat soluble vitamins and according to the primary references and 228, the compositions are free flowing.

Applicant's arguments that a prima facie case of obviousness cannot be established since the cited references do not alone or in combination teach, suggest or motivate one of ordinary skill in the art to arrive at the combination of elements recited in the instant claims are not persuasive since the all the references teach the use of silica

and that of Rawlins in particular teaches the use of silica of particle sizes of 50 microns. Since the upper limit of the vitamins taught Schmidt et al is 60 %, which is closer to instant 65 %, it is deemed obvious to one of ordinary skill in the art to vary the amounts of vitamins to obtain the best possible results. Therefore, applicant's arguments that the references do not teach higher loading densities are not persuasive

Applicant points out to col. 1, lines 46-50 and argues that 143 patent actually teaches away from using particle sizes of 40-50 microns since teaches that a minimum length, width or both of 300 microns is essential. This argument is not persuasive since the applied prior art in general teaches the applicability of hydrophobic silicas for obtaining free flowing compositions of active agents and as also pointed out above, silica particles from different companies appear to behave in different ways. It is unclear from 143 whether the silica used is from the company which sells sipernats and the reference of Rawlins clearly shows that one can use Sipernat 50 as the preferred silica to obtain free flowing compositions.

Rejection III: The examiner has already addressed applicant's arguments regarding Schmidt (4,486,435), Schmidt (4,603, 143) and Rawlins (4,719,228). Applicant argues that those of ordinary skill in the art recognize that large globular proteins such as enzymes, which are water soluble, and thus, require vastly different formulations than fat soluble vitamins and therefore, Drake reference is not relevant to small hydrophobic molecule formulation chemistry. These arguments are not persuasive since the reference is combined for its teachings of moisture in starch affecting the stability of compositions upon storage and one of ordinary skill in the art would expect similar

stability of a composition by using redried starch if the active agents are susceptible to moisture. This function of redried starch would remain the same irrespective what the active agent is.

The rejection is maintained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Gollamudi S Kishore, Ph.D/

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